MORRISON | FOERSTER

Morrison & Foerster Client Alert.

February 2010

# McCain Proposal Would Strengthen FDA Oversight of Dietary Supplement Industry

By Arturo González, William Tarantino, and Alexis Amezcua

On February 2, 2010, Senator John McCain, R-Ariz., introduced legislation that would strengthen the U.S. Food and Drug Administration's (FDA) oversight of the growing dietary supplement industry. Known as the Dietary Supplement Safety Act of 2010, the bill would usher in sweeping changes to the Federal Food, Drug, and Cosmetic Act (FDCA). Dietary supplement manufacturers and retailers should take heed. Such changes could significantly affect their responsibilities to the FDA, as well as expose them to potential litigation.

After years of claiming it needed greater authority, the FDA would, under the proposed legislation, finally have the power to issue a mandatory recall under various circumstances, including if it found a reasonable probability that a dietary supplement would cause serious, adverse health consequences.

The Act includes a number of changes of which dietary supplement manufacturers should be aware. A few of the highlights include:

- Dietary supplement facilities would be required to register with the FDA by providing the name and address of each facility at which, and all trade names under which, the dietary supplement facilities do business. At the time of registration, the dietary supplement registrant would also file with the FDA a list of all dietary supplements manufactured, packaged, held, distributed, labeled, or licensed by the facility.
- As of now, dietary supplement manufacturers need only provide the FDA with information regarding the safety of a new dietary ingredient if the ingredient was not marketed in the United States before October 15, 1994. 21 U.S.C. § 350b(a). The proposed bill would delete such a limitation and instead require that all new ingredients be substantiated as safe unless they are included on the list of Accepted Dietary Ingredients, as maintained by the FDA.
- In addition to the penalties presently available to the FDA, it would now have the authority to fine violators *up to twice the gross profits* derived from the manufacture, packaging, holding, distribution, labeling, or license of a dietary supplement.
- Dietary supplement facilities would have to report *all* adverse events, not only the serious adverse events they are currently required to report.

For the first time, retailers would also be responsible for the legal compliance of its suppliers under the FDCA. This bill would require dietary supplement facilities, as well as retailers, to obtain adequate written evidence from the preceding responsible entity in the chain of commerce that the product is appropriately registered with the FDA and the requirements for a new dietary ingredient are met.

Though there is no private right of action under the FDCA (21 U.S.C. § 310 *et seq*.), plaintiffs could argue that violation of these new provisions is a foundation for a claim of unlawful conduct under California's Business and Professions Code § 17200. The FDA's new recall and hefty penalty authority would also likely increase the number of manufacturers and retailers it targets for additional and more rigorous scrutiny.

Manufacturers and retailers alike should keep a watchful eye on the progress of the legislation, as it is bound to affect

day-to-day business processes, as well as potential legal liabilities. For further information on this topic and other consumer litigation matters, please contact Arturo González or William Tarantino.

### Contact:

Arturo González, (415) 268-7020, agonzalez@mofo.com

William Tarantino, (415) 268-6358, wtarantino@mofo.com

### About Morrison & Foerster:

We are Morrison & Foerster—a global firm of exceptional credentials in many areas. Our clients include some of the largest financial institutions, Fortune 100 companies, investment banks and technology and life science companies. Our clients count on us for innovative and business-minded solutions. Our commitment to serving client needs has resulted in enduring relationships and a record of high achievement. For the last six years, we've been included on *The American Lawyer*'s A-List. *Fortune* named us one of the "100 Best Companies to Work For." We are among the leaders in the profession for our longstanding commitment to pro bono work. Our lawyers share a commitment to achieving results for our clients, while preserving the differences that make us stronger. This is MoFo. Visit us at www.mofo.com.